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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,570	09/27/2001	Toshiya Kai	NPR-085	8923

20374 7590 10/29/2003

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 10/29/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/963,570

Applicant(s)

KAI ET AL.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,7-11 and 13-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 7-11, and 13-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendment C received on August 29, 2003 is acknowledged. Claims 1, 4, 7-11, and 13-22 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites a particle size of 75 microns to 1,700 microns; however claim 10 depends on parent claim 1 wherein the particle size is limited to 300 microns to 1,700 microns. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Rejection of claims 1, 4, 7-11, and 13-22 under 35 U.S.C. 102(b) as being anticipated by EP 0399918 is maintained.

EP teaches a powder dialysis preparation containing two compositions. The first composition contains 2188.7 parts sodium chloride particles with a coating layer of 35.6 parts magnesium chloride hexahydrate, 77.2 parts calcium monohydrate monohydrate,

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215.2 parts sodium acetate trihydrate, and acetic acid with instant particle sizes (examples 1-3). Examples and claims show that glucose particles are added to the electrolyte composition. See page 4 and 8-9. In example 2, sodium chloride is sprayed with an aqueous solution of the instant electrolytes are sprayed. The second composition contains glucose and sodium hydrogen bicarbonate with instant particle size (example 3).

In regards to the product-by-process claims see MPEP 2113.

Response to Arguments

Applicant argues that EP teaches the second composition to have sodium carbonate and glucose. Therefore, it is argued that EP does not teach glucose with the instant particles size. Applicant argues that it is important that the particle diameter of the second composition should be similar to that of the first composition. Applicant states that the process of making instant invention affords superior results compared to the prior art.

First, the examiner points out that the claim recites "core particles comprising particles of sugar, the core particles being covered with a coating layer comprising said sugar or different sugar." Once again the examiner points out that if a particle is coated with the same substance, then it is not different; therefore, glucose coated with glucose is glucose. Second, the examiner points out that the claims recite "a second composition comprising core particles of sugar...the second composition being granulated into granules having an average particle diameter of 300 to 1,700 microns." The claim language does not exclude additional coating layers on the sugar granules of

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the second composition. The claims merely limit the particle size of the granules of the second composition and not the glucose itself. Clearly on page 7, lines 24-25, EP discloses that the preferable particles range of the second composition is 12 to 100 mesh which equals 1700 microns to 150 microns. Therefore, EP anticipates that instant invention.

In regards to the unexpected results, the examiner points out that in unexpected results do not overcome anticipatory references.

Lastly in regards to applicant's statement that it is critical the particle size of the first composition and the second composition granules are similar, the examiner points out that EP teaches the first composition has a particle size of 14 to 100 mesh or 1400 microns to 150 microns and the second composition has a particle size of 1700 to 150 microns. These ranges are similar. In regards to the assertion that EP does not have a "homogenous content of glucose", the examiner points out that the applicant's arguments are based on features that are not recited in the claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Correspondence

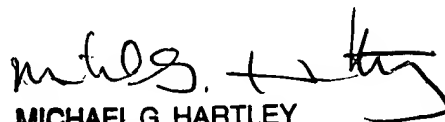
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG


10/21/03


MICHAEL G. HARTLEY
PRIMARY EXAMINER

MICHAEL G. HARTLEY
PRIMARY EXAMINER